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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,966	12/03/2003	Catherine A. Pipenhagen	47563.0012	4374

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EXAMINER	
WOO, JULIAN W	
ART UNIT	PAPER NUMBER
3773	
MAIL DATE	DELIVERY MODE
11/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/726,966	PIPENHAGEN ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/10/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33, 37-40, and 42-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,8,14,15,25,28-31,33,37-40,42,43 and 45-54* is/are rejected.

7)☒ Claim(s) *3, 6, 7, 9-13, 16-24, 26, 27, 32, 44, and 55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/10/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 10, "the tissue puncture sealing device" lacks antecedent basis.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 15, 28-30, and 47-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Rousseau (6,425,924). Rousseau discloses, in figures 1-4, a tissue puncture closure device in an undeployed configuration having a filament (22), an internal component or anchor (distal element 14), an external component

or a flexible sealing plug (another, proximal element 14 and 26 combined); where the internal component is configured to be positioned against an internal wall of a bodily lumen, where the external component is configured to be positioned external to the lumen, the external component being folded so one portion of the external component is in contact with another portion of the external component (at the folds), where the external component is operatively connected to the internal component by the filament, where the sealing plug comprises first (at 26) and second (at 14) pluralities of openings (the cells of the meshes), where the filament passes through one hole in the external component to a hole in the internal component and back through another hole in the external component, the external component being folded between the one hole and the another hole in the external component, where the filament only passes once through each one of the hole and the another hole, where a tension force applied to the filament compresses the sealing plug and the moves the sealing plug toward the anchor (See fig. 4), where the filament passes through at least two openings from the first plurality of openings (at 26 and 14), through the anchor, and back through at least two openings from the second plurality of openings (at 26 and 14), where the sealing plug is folded (at proximal element 14) and where the sealing plug has two legs (16) that form an at least approximately symmetrical shape, where the first and second pluralities of openings are respectively in the one and another legs.

5. Claims 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (5,545,178). Kensey et al. disclose, at least in

figures 1-9, a tissue puncture sealing device including a carrier tube (32), an anchor (38) disposed outside of the carrier tube at the first end thereof (e.g., at assembly of the device or at demonstration of the device outside of the device outside of a patient), a sealing plug (36) disposed inside the carrier tube at the first end thereof, where the sealing plug is folded at least once (See fig. 6), where the tissue puncture device is in an undeployed configuration where the tissue puncture device is not inserted into a patient (e.g., at assembly of the device or at demonstration of the device outside of a patient); and where the sealing plug is folded from an original V-shape (see fig. 6) to a rectangular shape (see fig. 1).

6. Claims 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Doan et al. (5,792,154). Doan et al. disclose, at least in figure 6 and in col. 4, line 56 to col. 5, line 4; a tissue puncture closure device including an anchor (137) configured to be inserted through a tissue puncture, a sealing plug (143) including separate first and second components (separate fibers 143), a filament (139 or 141) configured to couple the anchor and the sealing plug together when the anchor and the sealing plug are deployed, where the first and second components each have a U-shape and are in an interconnected relationship to each other.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

> obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 2, 4, 5, 8, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rousseau (6,425,924) in view of Eberbach (5,116,957). Rousseau discloses the invention substantially as claimed. Rousseau discloses a tissue puncture closure device including a filament passes through one hole in a sealing plug to a hole in an anchor and back through another hole in the sealing plug, where the one hole in the sealing plug is the last hole in the sealing plug (14) that the filament passes through before entering the hole in the anchor (another 14) and the another hole in the sealing plug is the first hole in the sealing plug (14) that the filament passes through after exiting the hole in the anchor, and where the filament passes through at least four hole in the sealing plug (14 and 26 combined), where the sealing plug (at 14) is folded at least twice, where the sealing plug is folded between the one hole in the sealing plug and the another hole in the sealing plug, where the sealing plug and filament each comprise biologically resorbable materials (See col. 4, lines 41-56), and the sealing plug shape comprises two components (14 and 26). However, Rousseau

does not disclose a carrier tube. Eberbach teaches, at least in figure 7 and in col. 3, lines 29-37; a carrier tube (10) for a tissue puncture closure device. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Eberbach, to include a carrier tube with the device of Rousseau. Such a tube would allow the precise delivery of Rousseau's device through a laparoscopic opening and into a surgical cavity without substantial interference from surrounding tissues.

9. Claims 25 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmieding (6,027,523). Schmieding discloses the invention substantially as claimed. Schmieding discloses, in figure 11, an internal tissue puncture closure device including an anchor (50, 52, 54, or 56), a filament, and a flexible sealing plug (42), where the sealing plug includes two cross members, where the sealing plug is formed of PLLA, which is an inherently flexible or compressible polymeric material, where applying a tension force to the filament moves the anchor and sealing plug together, and where the sealing plug is generally X-shaped in cross-section. However, Schmieding does not disclose that the filament extends through a plurality of holes in each of the two cross members, where the sealing plug is configured to compress when a tension force is applied to the filament. Nevertheless, Schmieding discloses a sealing plug (4) with a plurality of holes for receiving filaments (6, 36), where filaments 6 include knots configured to press upon the sealing plug when a tension force is applied to the filament. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to include a plurality of holes in each

of the two cross members. Such holes would allow convenient attachment of filaments to the sealing plug, while allowing at least two portions of a filament or two filaments to securely connect the sealing plug (and tissue) to the anchor. Moreover, filaments with knots applied with the sealing plug would allow compression of the sealing plug when tension is applied to the filament and allow a better securement of tissue to the anchor.

10. Claims 31, 37-40, 42, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (6,508,828). Akerfeldt et al. disclose the invention substantially as claimed. Akerfeldt et al. disclose, in figures 1, 4, and 6-18, a tissue puncture closure device and a method of sealing an internal tissue puncture having a carrier tube (24) or insertion sheath, and a closure device including an anchor (2) and a sealing plug (18) that is folded at least once or from a V-shape (fig. 18) into a substantially straight shape, and a filament (12), where applying a tension force to the filament compresses and holds the sealing plug and the anchor together (e.g., See figures 1 and 4). However, Adkerfeldt et al. do not disclose that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug, when the closure device is in an undeployed configuration before insertion into the internal tissue puncture (see fig. 8). Akerfeldt et al. also do not disclose that the sealing plug is in a V-shape when open and laid out flat. Nevertheless, Akerfeldt et al. disclose, in figures 15 and 17, that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug when parts 41 and 42 are moved along filament (12). Thus, it would have been obvious to one

having ordinary skill in the art at the time the invention was made, to move parts 41 and 42 within the carrier tube (as shown in figures 8, 10, and 11), so that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug (while the closure device is in an undeployed configuration within the carrier tube). Such a narrowed configuration of the sealing plug would ease its deployment through a puncture in a vessel.

Akerfeldt et al. also disclose, in col. 5, lines 4-7; that the sealing plug (18) comprises a polymeric material conforming to a suture (12) and is a thickened portion of a suture formed into a V-shape. Thus, it would have been obvious to one having ordinary skill in the art to form the sealing plug into a V-shape while the suture is open and laid out flat in a V-shape. Such a pre-formed shape for the sealing plug and suture would ease the assembly of the components of the device before its insertion into a tissue wall puncture.

Akerfeldt et al. also do not disclose that the anchor is positioned outside of the carrier tube. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to position the anchor outside of the carrier tube before its insertion within the carrier tube in a known technique of assembling the device prior to its deployment.

Allowable Subject Matter

11. Claims 3, 6, 7, 9-13, 16-24, 26, 27, 32, 44, and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination discloses a tissue puncture closure device having, inter alia, a carrier tube, a filament, an anchor, and a sealing plug or first external component, and a second external component folded and engaged with the first external component, where the filament passes through one hole in the external component to a hole in the internal component and back through another hole in the external component, where the sealing plug is shaped approximately like an S, where the sealing plug comprises a first plurality of holes forming a first weave pattern and a second plurality of holes forming a second weave pattern and where the filament passes through the pluralities of holes, where the sealing plug comprises an X-shape in cross-section, where the external component is collagen sponge where the sealing plug comprises an X-shape in cross-section and the filament alternately extends through holes in two cross members of the sealing plug in a spiral pattern, where the sealing plug is tri-folded into an S-shape as seen from an end, and where firs and second external components are each folded into generally U-shapes and the filament passes through one hole in the first component and one hole in the second component before passing through a hole in the anchor, and where the filament passes through another hole in the first component and another hole in the second component after passing through the hole in the anchor.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

13. Applicant's arguments filed on August 10, 2007 have been fully considered but they are not fully persuasive: See the restated and new grounds of rejection above.

The rejection of claims under 35 U.S.C. 102 and based on the reference of Nash et al. are hereby withdrawn.

With respect to arguments regarding the rejection under 35 U.S.C. 102 with the Rousseau reference: See the restatement of the rejection above, where the filament indeed passes through at least two openings (one opening from sheet 26 and one opening from upper conical element 14) from each of the first and second pluralities of openings of the flexible sealing plug, and where upper conical element 14, as well as sheet 26 (at least where the filament engages the sheet), are compressed when a tension force is applied to the filament.

The rejection under 35 U.S.C. 102 and based on theThal reference is hereby withdrawn.

With respect to arguments regarding the rejection based on the reference of Akerfeldt et al.: Before deployment of the device and at assembly, or even demonstration of the device, the anchor is obviously positioned outside of the carrier tube (before it, too, is inserted within the carrier tube). Moreover, tension force is indeed applied to the filament, when the filament is pulled for

engagement with the anchor and the sealing plug. The sealing plug, with its frictional engagement with the filament, the anchor, and element 6, also imparts tension upon the filament.

With respect to arguments regarding the rejection under 35 U.S.C. 103 with the Schmieding reference: Tension on filaments 6, for example, from pulling and tying (with knots) the filaments, does indeed result in moving the anchor and the sealing plug together.

With respect to arguments regarding the rejection under 35 U.S.C. 103 with the reference of Akerfeldt et al. and in contrast to Applicant's arguments: The Examiner did not assert that parts 41 and 42 are folded in the insertion sheath. The rejection did assert that the positioning of parts 41 and 42 next to each other results in the folding of the sealing plug (18), so that portions of the sealing plug contact each other.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo
Primary Examiner

November 1, 2007